UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services,

CENTERS FOR MEDICARE AND MEDICAID SERVICES, and

SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

Case No. 20-10488

ECF Case

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Regeneron Pharmaceuticals, Inc. (Regeneron) brings this complaint for declaratory and injunctive relief against Defendants United States Department of Health and Human Services (HHS); Alex M. Azar II, in his official capacity as Secretary of HHS; Centers for Medicare & Medicaid Services (CMS); and Seema Verma, in her official capacity as Administrator of CMS. In support thereof, Regeneron states the following:

NATURE OF THIS ACTION

1. The U.S. pharmaceutical industry is one of the marvels of the modern world. Every year the industry develops new treatments for diseases that have afflicted humans for millennia.

Even now, during a worldwide pandemic, U.S. pharmaceutical companies have been working around-the-clock in an unprecedented effort to discover vaccines, therapies, and other products to combat SARS-CoV-2, the virus that causes COVID-19.

2. The success of the U.S. pharmaceutical industry and the scientific advances that benefit patients have not come about by chance. A new drug can cost years of time and literally billions of dollars to develop. To encourage the pharmaceutical industry to incur those extraordinary costs, Congress has provided intellectual property protections but left drug pricing largely to the law of supply and demand, thus creating incentives for drug developers to expend the resources necessary for cutting-edge innovation. The resulting access that patients have to life-saving medicines is a testament to Congress' wisdom.

3. Many other countries, by contrast, have taken a different path, thus depriving patients access to innovative medicines. Because the pharmaceutical industry is characterized by enormous "sunk" costs (namely, the prior costs of discovering and developing new drugs) but low "marginal" costs (namely, the ongoing costs of manufacturing existing drugs), foreign governments—especially those with less innovative pharmaceutical industries—often dictate drug pricing that allows drug companies to recoup marginal costs but not sunk costs. Yet the only reason many drugs even exist is because they were developed in the United States, which rewards innovation and allows drug companies to charge prices that reflect *total* costs. If every country, including the United States, gave short shrift to sunk costs, there would be few innovative drugs to price as the incentives to develop new drugs would decrease if not disappear outright. Congress thus has repeatedly rejected proposals to model U.S. drug pricing on other countries' approaches.

4. Despite Congress' considered and consistent judgment not to follow foreign countries' approaches to drug pricing, on July 24, 2020, the President announced four executive

orders addressing pharmaceutical drug pricing. According to the President, "the four orders … will completely restructure the prescription drug market"—and the fourth is "the granddaddy of them all." This fourth order, "the order on favored nations," would be "transformative" and require Medicare to "purchase drugs at the same price as other countries pay." According to the President, the effect of the orders would be "very dramatic," "very shocking," and "sweeping"—resulting in "the most far-reaching prescription drug reforms ever issued."

5. The Administration released the text of the first three orders alongside the President's July 24 announcement. But it elected to "hold" the "transformative" fourth order out of public view, only issuing it on September 13. That order directed HHS to "implement" a rule whereby Medicare would, for certain drugs, pay "no more than the most-favored-nation price."

6. On November 20, 2020, HHS, acting through CMS, issued the rule previewed in July and September: a "Most Favored Nation (MFN) Model" for Medicare Part B drug pricing (the "MFN Rule"). The 258-page MFN Rule establishes an "MFN Model" under which, for the 50 drugs generally making up the highest levels of Medicare Part B spending, the federal government will reimburse a healthcare provider for the sale of a drug not at the average sale price for that drug in the United States—as Congress has directed by statute—but only at the lowest price paid for that drug by any other country that is a member of the Organisation for Economic Cooperation and Development (OECD) with a GDP per capita at least sixty percent of the U.S. GDP per capita. The "MFN Model" applies nationwide, is mandatory for all providers and suppliers in the Medicare program, and will be in effect for seven years beginning January 1, 2021.

7. In announcing the MFN Rule, the President called the rule "groundbreaking," "unprecedented," and a rule that "will transform the way the U.S. government pays for drugs."

The President acknowledged that "[n]obody has ever done this" before.

8. Upon issuance of the MFN Rule, it became clear why "[n]obody has ever done this" before: the MFN Rule, while certainly "transformative," "groundbreaking," and "the granddaddy" of "the most far-reaching prescription drug reforms ever issued," is also unlawful.

9. First, the 258-page "transformative," "groundbreaking," and "unprecedented" MFN Rule was issued without the notice-and-comment process required by the Administrative Procedure Act and the Medicare Act. Despite the fact that the MFN Rule, by design, will have sweeping effects on millions of stakeholders in the American healthcare system—including healthcare providers, patients, and pharmaceutical manufacturers—and impact the Nation's economy by billions of dollars, Defendants did not properly invite, much less consider, public input before issuing the rule. Defendants have instead claimed that they need not comply with the notice-and-comment requirement, an assertion that does not withstand scrutiny.

10. Second, the lone source of statutory authority Defendants have invoked to issue the MFN Rule is an obscure provision created by the Affordable Care Act. But the United States is currently telling the Supreme Court that the *entire* Affordable Care Act should be struck down. If Defendants stand by the arguments that the Solicitor General has made to the Supreme Court, then there is no conceivable statutory authority whatsoever for the MFN Rule. Regardless, the cited provision does not remotely support Defendants' effort to "transform" the Nation's pharmaceutical drug market. It merely establishes the Center for Medicare and Medicaid Innovation (CMMI) and provides that CMMI may "test" new "payment and service delivery models." Nothing in that limited statutory mousehole begins to justify the elephantine and "transformative" MFN Rule or otherwise permit Defendants to unilaterally replace the Nation's longstanding, congressionally mandated, market-driven methodology for pharmaceutical pricing.

11. Third, the MFN Rule is arbitrary and capricious. In their quest to force a nationwide pricing regimen, Defendants failed to create a control group to assess the effects of the MFN "model," and they failed to address critical considerations, including the rule's adverse effects on innovation, the pharmaceutical industry's reliance on longstanding drug pricing law, and the fact that some companies—like Regeneron—do not control the foreign pricing of products affected by the MFN Rule. The MFN Rule is also arbitrary and capricious because Defendants' *real* motivation for issuing the rule was animus against the pharmaceutical industry.

12. Fourth, interpreting the modest provision invoked by Defendants as authorizing the Executive Branch to "transform" the pricing of prescription drugs by overriding the congressionally established pricing system violates constitutional separation-of-powers principles. The MFN Rule also violates the First Amendment, the nondelegation doctrine, due process, and the Foreign Commerce Clause, and constitutes a taking without just compensation.

13. Because the MFN Rule was issued without following proper procedure, is in excess of Defendants' statutory and constitutional authority, and is arbitrary and capricious, it is unlawful and this Court should enjoin it. As Congress has recognized on numerous occasions, the pharmaceutical industry's long-term ability to innovate and find new cures and treatments for disease depends on the existence of a domestic pricing system that allows drug developers to recoup the *full* costs of drugs, including their development costs. Because the MFN Rule, by design, will prevent that from happening, judicial review is essential to protect the future of this important industry and the billions of people it serves.

PARTIES

14. Plaintiff Regeneron is a New York corporation with its headquarters in Tarrytown, New York. Regeneron was founded in 1988 as a biopharmaceutical company committed to developing new medicines for people with serious and rare diseases. The physician-scientists that

make up Regeneron's board of directors and executive leadership team established and maintained Regeneron's research-driven approach from 1988 to the present. Since Regeneron's founding, its board of directors—comprised of its founding scientists, industry experts, and Nobel laureates—has consistently pushed the boundaries of scientific excellence and discovery with a shared commitment to transforming lives. Currently, nine members of Regeneron's 12-member Board hold doctorate-level degrees in medical or scientific fields, and the majority are members of the National Academy of Sciences. Regeneron spent 20 years and $1.3 billion conducting research before bringing its first drug to market in 2008. Since then, the company has developed seven FDA-approved medicines, while continually reinvesting in the development of innovative and urgently needed drugs. One of Regeneron's FDA-approved medicines is EYLEA® (aflibercept) Injection (EYLEA), the leading FDA-approved therapeutic for treating wet age-related macular degeneration (a major cause of blindness) and other retinal diseases.

15. Defendant United States Department of Health and Human Services is a federal cabinet-level department tasked with administering various healthcare-related statutes. It is headquartered at 200 Independence Ave., S.W., Washington, DC, 20201.

16. Defendant Alex M. Azar II is Secretary of Health and Human Services. Secretary Azar is sued in his official capacity. He maintains offices at 200 Independence Ave., S.W., Washington, DC, 20201. Secretary Azar formally approved the MFN Rule on behalf of HHS.

17. Defendant Centers for Medicare & Medicaid Services is an agency within the Department of Health & Human Services that administers the Medicare and Medicaid programs. It is headquartered at 7500 Security Boulevard, Baltimore, MD, 21244.

18. Defendant Seema Verma is Administrator of Centers for Medicare & Medicaid Services. Administrator Verma is sued in her official capacity. She maintains offices at 27500

Security Boulevard, Baltimore, MD, 21244. Administrator Verma formally approved the MFN Rule on behalf of CMS.

JURISDICTION AND VENUE

19. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §1331. This action arises under, among other federal statutes, the Administrative Procedure Act (APA), 5 U.S.C. §§702 and 706, and the Declaratory Judgment Act, 28 U.S.C. §§2201-02. These provisions allow Regeneron to pursue both statutory and constitutional challenges to the MFN Rule. The All Writs Act, 28 U.S.C. §1651, grants this Court authority to enter preliminary relief to preserve the status quo pending its review of the merits of Regeneron's claims.

20. Venue is proper in this district pursuant to 28 U.S.C. §1391(e) because Regeneron is headquartered and resides in this district and its injured property is located in this district.

FACTUAL ALLEGATIONS

I. Pharmaceutical Pricing in the United States

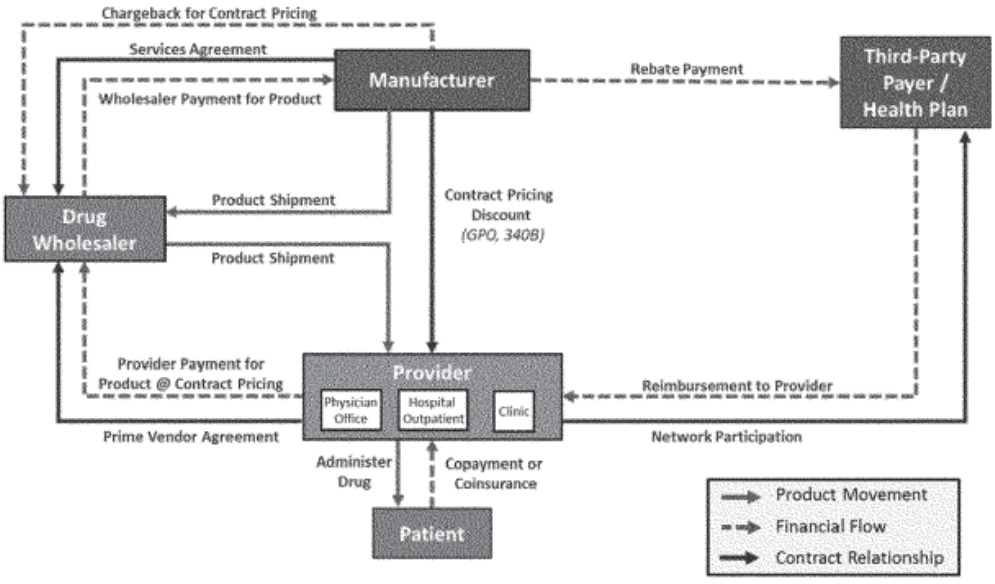
21. The U.S. pharmaceutical industry has rightly been labeled a modern miracle. Because of today's drugs, many diseases that have afflicted mankind since time out of mind have been defeated or are in significant retreat. Indeed, at this very moment, pharmaceutical companies like Regeneron are working around-the-clock to develop, manufacture, and distribute vaccines and therapies against SARS-CoV-2, the virus that causes COVID-19.

22. Congress has deliberately created a legal system that encourages pharmaceutical companies to invest the extraordinary sums necessary to develop new drugs, a process that can take years of time and billions of dollars. Congress has provided patent protection to drug developers and then largely left drug pricing to the law of supply and demand. Drug manufacturers in the United States thus are generally free to charge a price that reflects not only the "marginal" costs of their products, but also the "sunk" costs associated with drug development.

23. Pharmaceutical developers and manufacturers like Regeneron generally sell drugs like those at issue here according to a "buy and bill" model. They first sell the drugs to wholesalers, who then sell those drugs to pharmacies, hospitals, doctors, and other healthcare providers. At the end of the chain, patients pay for the drugs either out of pocket or via insurance, often including government-funded insurance. Purchasers throughout the distribution chain (such as, for example, wholesalers or pharmacies) regularly attempt to negotiate for lower prices, for instance by joining in a group purchasing agreement or group purchasing organization.

24. The following chart, prepared by CMS, illustrates U.S. drug pricing:

FIGURE 1: BUY-AND-BILL SYSTEM FOR DISTRIBUTION AND REIMBURSEMENT OF PROVIDER-ADMINISTERED OUTPATIENT DRUGS



GPO = Group Purchasing Organization; 340B = 340B Drug Pricing Program. Chart illustrates flows for **Provider-Administered, Outpatient Drugs.** Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016–17 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Drug Channels Institute, September 2016, Exhibit 28. Available at http://drugchannelsinstitute.com/products/industry_report/wholesale/.

25. Because each step along the distribution chain involves a change of title, each purchaser of a drug along the chain typically pays a different price. A manufacturer's price to a wholesaler is typically based on that drug's Wholesale Acquisition Cost (WAC) which is defined

as "the manufacturer's list price" to "wholesalers or direct purchasers," "not including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. §1395w-3a(c)(6)(B). The WAC, however, typically is higher than the actual price that a wholesaler charges. This is so because of, among other things, manufacturer rebates and discounts that reduce acquisition costs downstream.

26. Insurance is a key part of the U.S. healthcare market, including for drugs. Indeed, either private or government insurance will often pay a significant portion of the cost of a drug. Patients, by contrast, typically will pay a smaller portion via an out-of-pocket payment. That out-of-pocket payment is determined by a patient's deductible, as well as his or her co-payments and co-insurance. A co-payment is a fixed cost that an individual must pay for a particular drug, while co-insurance is a percentage of a drug's price that an individual must cover.

27. In the United States, approximately half of the population receives private health insurance through their employers, roughly 15% of the population is uninsured or has some other form of private insurance, and the rest of the population receives government health insurance. Approximately 20% of the population receives Medicaid and 15% receives Medicare. *See, e.g.*, *Health Insurance Coverage of the Total Population*, Kaiser Family Found., https://www.kff.org/other/state-indicator/total-population; Edward R. Berchick et al., *Health Insurance Coverage in the United States: 2017*, U.S. Census Bureau (Sept. 12, 2018), https://www.census.gov/content/census/en/library/publications/2018/demo/p60-264.html.

28. In terms of expenditures, Medicare is the country's largest government health insurer, accounting for 20% of all national health spending. *See, e.g.*, Juliette Cubanski et al., *The Facts on Medicare Spending and Financing*, Kaiser Family Found., (Aug. 20, 2019), https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing. Those eligible for Medicare include individuals aged 65 years or older, as well as certain persons with

disabilities. Medicare contains several "parts"—Parts A, B, C, and D. Part A covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care. Part B covers certain doctors' services, outpatient care, medical supplies, and preventive services. Part C is an alternative to "original Medicare." Part D adds prescription drug coverage to various insurance plans. Medicare.gov, *What's Medicare?*, https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare. Both Part B and Part D cover drugs, but Part B drug coverage existed before Congress created Medicare's Part D drug benefit and tends to cover drugs that are unusually complicated or treat especially serious diseases. *See, e.g.*, Dept. of Health & Hum. Servs., *Drug Coverage under Different Parts of Medicare*, (May 2020), https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf.

29. In 2003, Congress changed the nation's reimbursement policy for Medicare drugs. Before 2003, reimbursement was largely based on a drug's AWP. Now, however, Congress has mandated use of Average Sales Price (ASP) reimbursement. *See* 42 U.S.C. §1395w-3a; 42 C.F.R. §414.800 *et seq.* As its name suggests, the amount of ASP reimbursement is based on the average of most sales prices for a drug in the United States, including privately-negotiated discounts or rebates. ASP reimbursement rates, therefore, are often lower than list prices.

30. ASP is calculated as follows. First, one must calculate a "manufacturer's sales [of a drug, in dollars] to all purchasers [other than exempt sales] in the United States … in the calendar quarter." 42 U.S.C. §1395w-3a(c)(1)(A). That number is then divided by "the total number of such units of such drug … sold by the manufacturer in such quarter." *Id.* §1395w-3a(c)(1)(B). That is, ASP is the average net price at which the manufacturer sells a drug during a calendar quarter to all U.S. purchasers, excluding exempt sales. Exempt sales, in turn, include sales to various government entities or otherwise discounted by various provisions of federal law. *Id.*

§1395w-3a(c)(2). Manufacturers must report ASP data to CMS for most Part B drugs. Manufacturers report this data each quarter. Under federal law, the reimbursement rate equals 106% of a volume-weighted ASP, which CMS calculates based on manufacturers' reported ASPs and quarterly sales volumes. *Id.* §1395w-3a(c)(1). Since 2013, following budget sequestration, the reimbursement rate equals 104.3% of ASP. *See, e.g.*, Dept. of Health & Hum. Servs., *Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013* (Feb. 2015), http://oig.hhs.gov/oei/reports/oei-03-14-00520.pdf.

31. Accordingly, under Medicare Part B, Congress has determined that reimbursement rates should be based on the actual prices that drug developers and manufacturers charge on the open market, without price controls that artificially limit what drug developers and manufacturers can charge, for instance by tying prices to a drug developer's marginal costs. In other words, under Medicare Part B, government insurance payments for drugs are generally not materially different from what private insurers pay in terms of the amount per drug that manufacturers and developers receive for the drugs that they sell. This means that the price charged for a drug can reflect the *full* costs of the drug, including marginal and sunk costs.

32. Congress has repeatedly rejected efforts to impose price controls on drugs in the United States, including reimbursement rates for Part B drugs. Congress has refused to impose price controls because it recognizes that although price controls may be politically popular at first blush, such a policy would not, in fact, benefit the United States, given the deleterious effects price controls would have on supply and innovation.

33. Congress' decision to leave drug pricing largely up to the law of supply and demand, without price controls, has resulted in tremendous health benefits to the public. Nearly 7,000 drugs are currently in development around the world, with more than *half* of that

development occurring in the United States. The United States' approach to drug pricing thus has created a seedbed for innovation, with significant benefits to those living today and for future generations. As the U.S. Council of Economic Advisers, a group of government economists, has pointedly noted, lowering reimbursement rates for drugs in the United States "makes better health costlier in the future by curtailing innovation." Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

II. Pharmaceutical Pricing in Other Nations

34. In the United States, drug developers are free to charge prices that allow them to recoup both sunk and variable costs. Many other countries, however, have policies that make it difficult if not impossible for drug developers to recoup their sunk costs. During his 2019 State of the Union address, the President referred to this dynamic as "global freeloading," arguing that foreign countries do not pay a proportionate share of the costs necessary to develop drugs, but instead leave the United States to shoulder that burden alone.

35. Many foreign governments directly provide health care to individuals within their geographic boundaries. This means that governments or government-controlled entities are the principal purchaser of healthcare products, including drugs. Because these governments and government-controlled entities act as monopsonists (*i.e.*, the single purchaser) or near-monopsonists, they regularly can dictate prices for healthcare products, including drugs, as a condition of market access. Because drug developers cannot continue to sell drugs if they cannot at least recoup their marginal costs, foreign governments regularly set a price that is at or above marginal cost but below total cost. That is, foreign governments set prices that do not reflect the sunk costs necessary to develop a drug in the first place.

36. As the U.S. Council of Economic Advisers has explained:

> [I]n price negotiations with manufacturers, foreign governments with centralized pricing exploit the fact that once a drug is already produced, the firm is always better off selling at a price above the marginal cost of production and making a profit, regardless of how small, than not selling at all. Thus, the foreign government can insist on a price that covers the marginal production cost—but not the far greater sunk costs from years of research and development—and firms will continue to sell to that country.

Reforming Biopharmaceutical Pricing at Home and Abroad at 14.

37. Foreign governments also have indirect tools to set prices below the free-market price. For instance, foreign governments often require international reference pricing, a "system whereby a country states that they will pay no more than the price paid by another country or a basket of countries." Jason Shafrin, *International Reference Pricing*, Healthcare Economist (July 21, 2015), https://www.healthcare-economist.com/2015/07/21/international-reference-pricing. This means that if a drug developer sells a drug at one price in a poorer country (where residents may not be able to afford a price that includes both sunk and marginal costs), they may be required to also sell the drug at the same price in a wealthier country. Absent such indirect price controls, a drug developer could set prices in each region according to ordinary supply and demand conditions in that region. Accordingly, the result of international reference pricing is also prices that do not reflect the sunk costs necessary to develop the drug.

38. Foreign governments also regularly impose therapeutic reference pricing. This essentially means new medicines must be priced similarly to old medicines. *See, e.g.*, Jason Shafrin, *Cancer drug pricing in Europe*, Healthcare Economist (Nov. 14, 2016), https://www.healthcare-economist.com/2016/11/14/cancer-drug-pricing-in-europe/ ("The pricing considers both patented and generic drugs and generally compares drugs to therapeutic equivalents."). Older medicines, however, have, by definition, been in the marketplace longer, thus giving their developers more time to recoup sunk costs. Older drugs therefore are often sold

with prices set above marginal costs but with little to no concern about sunk costs. New medicines, by contrast, require new investments. The predictable consequence of therapeutic reference pricing thus is also prices that do not incorporate the sunk costs required to innovate.

39. Foreign governments may also decide to cut out the drug developer altogether. For instance, they may require compulsory licensing, whereby drug developers have no choice but to license their drugs to government-controlled manufacturers. *See, e.g.*, Jason Shafrin, *Pharmaceuticals in Developing Countries*, Healthcare Economist (May 18, 2008), https://www.healthcare-economist.com/2008/05/18/pharmaceuticals-in-developing-countries/ ("Brazil has 'threatened to invoke compulsory licensing (a legal mechanism that, in effect, legitimises such trampling [of patent rights]) to browbeat a foreign drugs firm into offering huge discounts.'"). The threat of compulsory licensing, moreover, may be used as a negotiating ploy to force drug developers to charge prices that do not cover sunk costs. Similarly, foreign governments may discriminate against U.S. companies, treating them less favorably than their domestic competitors.

40. By directly and indirectly forcing drug developers to set prices below total costs, these and other measures by foreign governments may lead to drug shortages (as the amount demanded at the artificially low price will exceed the amount supplied at that price) and discourage investment, as rational drug developers will not invest the immense time and resources necessary to develop drugs if the associated sunk costs cannot be recouped. As a group of over 150 economists recently explained, "setting price controls at below-market rates leads to shortages," and "can lead to a reduction in patient access to certain drugs, less investment in the research and development of new drugs, and cost-shifting that raises the prices of other therapeutics. Ultimately, patients … suffer as cures are delayed or entirely undeveloped, while taxpayers [are]

denied potential savings from drugs that could obviate more expensive treatments in government healthcare programs, and the investment of capital in development of new medicines." Letter to Alex M. Azar, Sec'y of Health & Hum. Servs. (Dec. 6, 2018), https://www.ntu.org/library/doclib/2018/12/Economists-Letter-to-HHS-1.pdf.

41. These concerns are backed by evidence. It is well-documented that price controls result in both less innovation and greater shortages. For instance, nearly 90% of new drugs launched around the world since 2011 are available in the United States; by contrast, Germany and the United Kingdom only have access to 60% of such drugs. *See* Comments of Pharmaceutical Research and Manufacturers of America at 5 (Dec. 2018), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_IPIModelComments.pdf. The situation is even worse in Canada and France, where less than half of these drugs are available. *See id.* And even when new drugs do become available in foreign markets, there often have been significant delays. *See id.* ("International reference pricing has been shown to contribute to launch delays, reduce product availability, and reduce research and development of new treatments and cures."). These differences have life-or-death consequences; for example, "[t]he 5-year survival rate for all cancers is 42 percent higher for men and 15 percent higher for women in the United States than in Europe." *Id.* at 7. Similarly, researchers have concluded that "implementing price setting policies in the United States would reduce life expectancy among Americans age 55 to 59 years old by 0.5 years in 2030 and 0.7 years in 2060." *Id.*

III. The October 2018 Proposed International Pricing Index Rule

42. On October 30, 2018, CMS issued an advance notice of proposed rulemaking for a model linking reimbursement prices for certain drugs under the Medicare Part B program to an "international pricing index"—the "IPI Rule." 83 Fed. Reg. 54546 (Oct. 30, 2018).

43. Under the IPI Rule, the federal government would have surveyed drug prices from

a list of 14 purportedly economically similar countries and then set a reimbursement rate for a drug based on the average price those countries pay for the drug, rather than the average-sales-price methodology that Congress mandated.

44. The IPI Rule would not have applied to the entire United States. Rather, it was directed to Part B drugs that are separately reimbursable in the Medicare system in certain parts of the country.

45. In the advance notice of proposed rulemaking, CMS invited a "general solicitation of comments" regarding a potential IPI approach. It expressly noted that any IPI approach it ultimately promulgated would be "implement[ed] through notice and comment rulemaking." It stated that it was "considering issuing a proposed rule in the Spring of 2019 with the potential model to start in Spring 2020."

46. The IPI Rule was sharply criticized, and it ultimately died on the vine. CMS never even advanced to issuing a notice of proposed rulemaking regarding the rule.

47. Instead, in January 2019, the President asserted in his State of the Union address that "[i]t's unacceptable that Americans pay vastly more than people in other countries for the exact same drugs, often made in the exact same place," and he "ask[ed] Congress to pass legislation that finally takes on the problem of global freeloading."

48. Congress did not enact any such legislation.

IV. The President's July and September 2020 Announcements Regarding an MFN Rule

49. On July 24, 2020—just three-and-a-half months before the presidential election—the President announced four executive orders related to drug prices. According to the President, "the four orders … will completely restructure the prescription drug market"—and the fourth would be "the granddaddy of them all." This fourth order, "the order on favored nations," would be "transformative" and require Medicare to "purchase drugs at the same price as other countries

pay," thereby "ensur[ing] that the United States pays the lowest price available in economically comparable countries." According to the President, the effect of the orders would be "very dramatic," "very shocking," and "sweeping"—resulting in "the most far-reaching prescription drug reforms ever issued."

50. The press release accompanying the announcement of the four executive orders advertised its lack of statutory authority. It was titled, "Congress Didn't Act on Prescription Drug Prices. So President Trump Did." *See* Press Release, (July 27, 2020), https://www.whitehouse.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did.

51. The Administration released the text of the first three orders alongside the President's July 24 announcement. But it elected to "hold" the "transformative" fourth order out of public view until "August 24th," in an effort to gain leverage over pharmaceutical companies during negotiations. As the President stated at the time, if those negotiations proved "successful, we may not need to implement the fourth executive order, which is a very tough order for them."

52. August 24 came and went, however, without further executive action.

53. On September 13, 2020, the President issued the fourth order, entitled "Executive Order on Lowering Drug Prices by Putting America First." The order announced that "[i]t is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price." Executive Order at Section 2 (Sept. 13, 2020), https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/. The order directed the Secretary of Health and Human Services, "[t]o the extent consistent with law," to "immediately take appropriate steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay,

for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." *Id*. at Section 3.

54. HHS took no public action in September or October regarding any "most-favored-nation" rule.

V. The MFN Rule

55. On November 3, 2020, the presidential election took place.

56. In mid-November 2020, media sources reported that the President's advisors had resurrected the idea of a most-favored-nation pricing rule, arguing it would "hit an industry that Trump believes slow-walked coronavirus vaccine development until after the election." Sarah Owermohle and Dan Diamond, *Trump seeks final stamp on drug prices with sweeping rule*, Politico (Nov. 17, 2020), https://www.politico.com/news/2020/11/17/trump-seeks-final-stamp-on-drug-prices-with-sweeping-rule-437191. Sources stated that the renewed interest in the long-dormant plan to cap drug reimbursements came after the President privately railed against Pfizer for not revealing until after Election Day that its coronavirus vaccine was ninety percent effective. *Id*.

57. On November 20, 2020, CMS issued the MFN Rule.[1] Comprising 258 pages, the MFN Rule implements a supposed "model," administered by the CMMI pursuant to 42 U.S.C. §1315a, under which the federal government, for dozens of Medicare Part B drugs, will reimburse a healthcare provider for the sale of a drug not at the average sale price for that drug in the United States—as Congress has directed by statute—but only at the lowest price paid for that drug by any other country that is a member of the OECD with a GDP per capita at least sixty percent of the

[1] The MFN Rule was formally published in the Federal Register on November 27, 2020. *See* 85 Fed. Reg. 76180 (Nov. 27, 2020).

U.S. GDP per capita (deemed the "MFN Price"). Providers will also receive an add-on payment that does not depend on the price of the particular drug being reimbursed, and beneficiaries will pay co-insurance only on the reimbursement amount, not on the add-on payment.

58. The MFN "model" will operate for seven years beginning January 1, 2021, and ending December 31, 2027, with the first three years (2021 through 2023) phasing in the effect of the MFN Price by blending that price and the ASP price to determine the reimbursement rate. By 2024, the reimbursement rate is 100% composed of the MFN price.

59. The geographic coverage of the "model" is nationwide. And with extremely limited exceptions, the "model" requires the "mandatory participation" of all Medicare Part B providers.

60. During the first program year, the "model" will apply to a set of fifty Medicare Part B drugs purportedly encompassing the highest percentage of Medicare Part B drug spending. During subsequent program years, additional drugs will be added to the "model" based on updated annual Medicare Part B spending; all drugs previously included in the program will continue to be included.

61. In the MFN Rule, CMS estimated that the rule would affect Medicare Part B spending by $85.5 billion. HHS estimated that the rule would affect Medicare Part B spending by $87.8 billion.

62. Regeneron's EYLEA is among the fifty drugs included for the first program year beginning January 1, 2021. Indeed, EYLEA is first on the MFN Rule's list of Medicare Part B drugs representing the highest Part B spending in 2019. And in CMS's Fact Sheet accompanying the MFN Rule, CMS specifically singled out EYLEA (and no other drugs), asserting that EYLEA "was approximately two times as expensive in Medicare Part B as in comparison countries." FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim

Final Rule with Comment Period, Center for Medicare & Medicaid Services (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule.

63. Regeneron does not and cannot control the pricing of EYLEA outside the United States. Outside the United States, EYLEA is marketed by Bayer, which has a license to Regeneron's intellectual property and solely determines pricing for EYLEA consistent with other nations' policies.

64. The President personally announced the issuance of the MFN Rule. In his remarks, the President described the rule as "the biggest ever, concerning drugs and drug pricing." Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans (Nov. 20, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans/. Describing the MFN Rule as the product of a "two year[]" process, the President characterized the rule as "unprecedented" and "groundbreaking," stating that it would "transform" the way the federal government "pays for drugs" and would "very dramatically lower the price of prescription drugs" by "savings of 50, 60, 70 percent, 80 percent"—"colossal savings." *Id.* He added, "Nobody has ever done this," and "there'll never be anything like this." *Id.*

65. The President and the HHS Secretary made clear in their remarks who will bear the burden of the "colossal savings" purportedly effected by the MFN Rule—pharmaceutical manufacturers like Regeneron. As the Secretary stated, the MFN Rule "boldly take[s] on the big drug companies." *Id.* The President added that "[t]he drug companies don't like me too much, but we had to do it," asserting that "the American people have been abused by big pharma and their army of lawyers, lobbyists, and bought-and-paid-for politicians." *Id.*

66. In his remarks, the President also tied the MFN Rule to pharmaceutical manufacturers' protected political speech, stating, "Big pharma ran millions of dollars of negative advertisements against me during the campaign … I told them, 'I'm going to have to do this.'" *Id.* And he also tied the rule to the timing of announcements about COVID-19 vaccine progress, remarking: "Pfizer and others were way ahead on vaccines.… Pfizer and others even decided to not assess the results of their vaccine; in other words, not come out with a vaccine until just after the election. That's because of what I did with favored nations and these other elements, instead of their original plan to assess the data in October. So they were going to come out in October, but they decided to delay it because of what I'm doing." *Id.*

67. Notwithstanding the MFN Rule's concededly "groundbreaking," "unprecedented," and "very dramatic[]" nature—which will "transform" drug pricing across the entire United States, resulting in "colossal savings" ultimately borne by pharmaceutical manufacturers—the MFN Rule was issued without compliance with the notice-and-comment process required by the Administrative Procedure Act and Medicare Act. Instead, CMS issued the 258-page rule—which was announced as the product of a "two year[]" process—as an interim final rule, bypassing proper notice-and-comment procedure because "high drug prices in the U.S. have serious economic and health consequences," which "the COVID-19 pandemic has rapidly exacerbated." For the same reason, CMS concluded that delaying implementation of the MFN Rule, as would ordinarily be required under federal law, would be "contrary to the public interest."

68. At no point in July 2020, when the President originally announced his proposed executive order regarding a most-favored-nation rule, or in September 2020, when the President finally issued that order later than initially promised, did the executive branch link the order to the COVID-19 pandemic or invoke the pandemic as a justification for expediting the rule. To the

contrary, the MFN executive order was held back for seven weeks after the companion executive orders were publicly issued.

69. Meanwhile, ten days before Defendants issued the MFN Rule, the Acting Solicitor General of the United States told the Supreme Court of the United States that the entire Affordable Care Act—which created the lone source of statutory authority on which the MFN Rule relies—is invalid. In that case, *California v. Texas* (consolidated with *Texas v. California*), the Supreme Court is considering whether the so-called "individual mandate" of the ACA is unconstitutional following Congress' decision in 2017 to eliminate the monetary penalty associated with the mandate. The United States has argued not only that the individual mandate is unconstitutional, but that the remainder of the ACA is not severable, and therefore "[t]he entire ACA … must fall with the individual mandate." Br. of United States at 13, *California v. Texas*, No. 19-840 (U.S. June 25, 2020). That is the same position that the United States took when the case was in the court of appeals. *See* Br. of United States at 3, *Texas v. United States*, No. 19-10011 (5th Cir. May 1, 2019) ("[I]t is the position of the United States that the balance of the ACA also is inseverable and must be struck down.").

70. Implementation of the MFN Rule will—as Defendants intended and anticipated—have significant adverse effects on Regeneron, including extraordinary monetary harm that cannot be recovered, irreparable competitive and reputational injury, and notice-based and constitutional injury.

COUNT I
(Violation of Administrative Procedure Act—Failure to Provide Notice and Comment)

71. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

72. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. §2201(a).

73. The Administrative Procedure Act (APA) provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. §702.

74. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." *Id.* §704.

75. The APA further provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions" found to be, inter alia, "(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] (D) without observance of procedure required by law." *Id.* §706(2).

76. The MFN Rule was issued "without observance of procedure required by law."

77. The APA requires agencies, before promulgating a rule, to publish a "[g]eneral notice of … rule making" in the Federal Register and to provide the public with "an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. §553(b)-(c).

78. The Medicare Act provides that CMS cannot "issue[] in final form any regulation" of the sort here unless it "provide[s] for notice of the proposed regulation in the Federal Register

and a period of not less than 60 days for public comment thereon." 42 U.S.C. §1395hh(b)(1).

79. In promulgating the MFN Rule, Defendants did not provide for notice and comment as required by the APA and the Medicare Act.

80. Defendants' stated reason for forgoing the notice and comment required by the APA and the Medicare Act—because "high drug prices in the U.S. have serious economic and health consequences," which "the COVID-19 pandemic has rapidly exacerbated"—largely repeats longstanding views advanced in the context of abandoned rulemakings and unsuccessful pushes for legislative action and does not satisfy the narrow "good cause" standard for bypassing notice and comment.

COUNT II
(Violation of Administrative Procedure Act—Exceeding Statutory Authority)

81. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

82. The MFN Rule is "in excess of statutory jurisdiction, authority, or limitations" in multiple respects.

83. The only statutory authority invoked by Defendants for the MFN Rule is Section 1115A of the Social Security Act, 42 U.S.C. §1315a, which was created by Section 3021 of the Affordable Care Act. *See* Pub. L. No. 111-148, §3021, 124 Stat. 389-95 (2010). But the United States is currently insisting in the Supreme Court that some provisions of the ACA are unconstitutional and that no provision of the ACA is severable or capable of valid independent operation. If Defendants stand by the arguments they are making to the Supreme Court, then there is simply no authority whatsoever for the MFN Rule, which relies on a statutory provision (and entity) created by the Affordable Care Act.

84. In all events, Section 1115A does not authorize the MFN Rule. That provision is

designed to allow CMMI to test pilot programs. It authorizes CMMI to "test payment and service delivery models … to determine the effect of applying such models … on program expenditures … and the quality of care received by individuals receiving benefits." 42 U.S.C. §1315a(b)(1). The sweeping framework imposed by the MFN Rule does not constitute a "model" as that term is used in Section 1115A, and thus the MFN Rule is not authorized by Section 1115A.

85. Additionally, in Section 1115A, Congress has not clearly authorized CMS to fundamentally transform drug pricing in the United States. Congress must speak clearly if it wishes to assign to an agency decisions of vast economic and political significance; it does not "hide elephants in mouseholes." The MFN Rule is a transformative initiative of elephantine scale, as the President's own remarks underscore. Yet Section 1115A is a statutory mousehole, and Congress has certainly not clearly authorized what the MFN Rule purports to accomplish. To the contrary, Congress has expressly and repeatedly rejected proposals that would tie U.S. drug prices to international prices or otherwise prevent drug developers from recouping their sunk costs.

COUNT III
(Violation of Administrative Procedure Act—Arbitrary and Capricious Agency Action)

86. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

87. An agency acts arbitrarily and capriciously under the APA when it fails to examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made. Agency action is also unlawful if the agency has relied on factors that Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. Further, an agency must be cognizant that longstanding policies

may have engendered serious reliance interests that must be taken into account. A rule is also arbitrary and capricious if the agency committed a clear error of judgment or if its explanation for its decision is not sufficient to enable the court to conclude that it was the product of reasoned decisionmaking.

88. The MFN Rule is arbitrary and capricious because Defendants did not consider the factors Congress told Defendants to consider. In Section 1115A, Congress made clear that CMS "shall" select models where "there is evidence that the model addresses a defined population for which there are deficits in care" leading to "poor clinical outcomes or potentially avoidable expenditures." But Defendants have simply identified the "defined population" as *all* Medicare Part B beneficiaries who receive *any* of the 50 listed drugs *anywhere* in the country from *any* provider or supplier. CMS has identified no "evidence" of an actual "defined population" suffering from "deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." Congress also instructed CMS to "test" a "model," but the nationwide MFN Rule contains no control group, so there is nothing to measure the MFN Rule against.

89. The MFN Rule is also arbitrary and capricious because Defendants failed to consider important aspects when issuing the rule, including (1) the MFN Rule's adverse effects on innovation and public health, (2) reliance interests based on longstanding drug pricing law that encouraged pharmaceutical manufacturers to invest in billions of dollars in research and development, and (3) the inability of some manufacturers, like Regeneron, to control the prices of certain drugs outside the United States, such that they neither created nor can rectify the purported "global freeloading" problem identified as a basis for the MFN Rule.

90. The MFN Rule is further arbitrary and capricious if its real justification was to punish the pharmaceutical industry because some manufacturers supposedly withheld positive

results regarding a COVID-19 vaccine until after the presidential election, and also for purportedly running negative advertisements against the President's re-election.

COUNT IV
(Violation of Administrative Procedure Act—Contrary to U.S. Constitution—Violation of Separation of Powers)

91. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

92. Pursuant to 5 U.S.C. §706, a "reviewing court shall … hold unlawful and set aside agency action, findings, and conclusions found to be … contrary to constitutional right, power, privilege, or immunity" or "otherwise not in accordance with law." 5 U.S.C. §706(2)(A)-(B).

93. Article I of the U.S. Constitution specifies how legislative power can be exercised, providing that "[a]ll legislative Powers herein granted shall be vested" in Congress, and "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States." U.S. Const. art. I, §§1, 7 cl. 2. These provisions, known as bicameralism and presentment, are integral parts of the constitutional design for the separation of powers. Accordingly, the President cannot effect the repeal of laws without observing the procedures set out in the Constitution.

94. The Constitution also prohibits Congress from transferring its legislative powers to a federal agency. Because federal agencies can only execute the law, rather than make it, when Congress delegates authority to agencies, Congress must also provide an "intelligible principle" to guide the agency's exercise of the delegated authority. The more expansive the authority, the more specific that intelligible principle must be.

95. The MFN Rule violates these constitutional principles. The MFN Rule requires Defendants to waive numerous critical sections of longstanding statutory law throughout the entire country for seven years, effecting a repeal of Congress' legislative scheme without bicameralism

and presentment. Furthermore, Congress cannot give the Executive Branch the unilateral power to change the text of duly enacted statutes, and there is no intelligible principle to guide Defendants' efforts to fundamentally change U.S. drug pricing.

COUNT V
(Violation of Administrative Procedure Act—Contrary to U.S. Constitution—Violation of First Amendment)

96. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

97. The First Amendment protects speech, including the choice of both what to say and what *not* to say.

98. Defendants promulgated the MFN Rule to retaliate against the entire pharmaceutical industry for engaging in protected First Amendment speech, namely drug manufacturers' "negative advertisements" during the 2020 presidential campaign and speech related to the production and success of a COVID-19 vaccine.

99. Retaliating against the pharmaceutical industry for protected political speech and for decisions about when to speak and when not to speak about a coronavirus vaccine clearly violates the First Amendment's free speech protections. Because Defendants promulgated the MFN Rule in retaliation against the pharmaceutical industry in this way, the MFN Rule is unconstitutional and violates the First Amendment.

COUNT VI
(Violation of Administrative Procedure Act—Contrary to U.S. Constitution—Violation of Foreign Commerce Clause)

100. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

101. Article I, Section 8 of the U.S. Constitution empowers Congress "[t]o regulate Commerce with foreign Nations." Because this power is exclusively given to Congress, an agency

cannot regulate foreign commerce unless Congress has authorized it to do so.

102. The MFN Rule violates the Foreign Commerce Clause because, in intent and effect, it substantially and directly affects foreign commerce. The President openly acknowledged that the rule was intended to "end global freeloading"—a statement that only makes sense if one of the purposes of the MFN Rule is to *increase* foreign prices. The rule itself states that CMS "expect[s]" drug manufacturers to "devote considerable resources" to "altering the availability and terms of their international prices," which likewise contemplates purposeful, direct regulation of foreign commerce.

103. Congress, however, has not authorized such regulation of foreign commerce.

COUNT VII
(Violation of Administrative Procedure Act—Contrary to U.S. Constitution—Violation of Due Process)

104. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

105. The Fifth Amendment to the U.S. Constitution provides that the federal government may not "deprive" someone "of life, liberty, or property, without due process of law." Courts have recognized that the Due Process Clause contains a substantive component that protects the public from arbitrary government action.

106. The MFN Rule violates the Due Process Clause because it is arbitrary governmental action that destroys longstanding incentives to innovate, despite the fact that many drug developers relied on those incentives when making investment decisions, including as to research and development. At the same time, the MFN Rule nullifies significant investments that have already occurred because drug developers, including Regeneron, acting in reliance on statutory law, have invested substantial resources necessary to develop drugs. Such statutory law allows Regeneron to charge prices that enables recoupment of those extraordinary sunk costs. By contrast, the MFN

Rule artificially deflates drug prices, thereby significantly reducing the value of Regeneron's intellectual property and other assets, despite Regeneron's significant reliance interests. And although the MFN Rule proceeds on the premise that pharmaceutical companies are charging too little in other countries, and contemplates that pharmaceutical manufacturers could alleviate some of the rule's harm to them by raising foreign prices, Regeneron cannot do so, as its pricing outside the United States is controlled exclusively by Bayer.

COUNT VIII
(Violation of Administrative Procedure Act—Contrary to U.S. Constitution—Taking Without Just Compensation)

107. Regeneron realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

108. The Fifth Amendment to the U.S. Constitution provides that "private property" shall not "be taken for public use, without just compensation." This constitutional provision bars both physical and regulatory takings.

109. A taking may be found based on a complex of factors, including (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action. The ultimate question is whether the government has forced the owner to bear public burdens that, in all fairness and justice, should be borne by the public as a whole.

110. The MFN Rule will have a profound economic impact on Regeneron's business and will upend Regeneron's investment-backed expectations. Regeneron has spent billions of dollars developing drugs based on a model that Congress enacted and that Defendants now purport to have unilaterally replaced. Statutory law allows Regeneron to charge prices that enable recoupment of those extraordinary sunk costs. But the MFN Rule artificially deflates drug prices, thereby significantly reducing the value of Regeneron's intellectual property and other assets. The

MFN Rule thus constitutes an uncompensated taking of Regeneron's intellectual property and other assets that defeats Regeneron's investment-backed expectations.

PRAYER FOR RELIEF

WHEREFORE, Regeneron prays that this Court:

A. Issue an order and judgment declaring that Defendants violated the APA in issuing the MFN Rule because the MFN Rule was issued without following proper procedure; is in excess of statutory authority; violates the Constitution; and is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law.

B. enjoin implementation and enforcement of the MFN Rule;

C. award costs and attorneys' fees pursuant to any applicable statute or authority; and

D. provide such other and further relief as the Court may deem just and appropriate.

Respectfully submitted,

Dated: December 11, 2020

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